

REMARKS

Claims 80, 81, and 83-93 remain pending in this application. Claims 80, 81, and 83-93 stand rejected. Applicants reserve the right to file a continuation or divisional application claiming the subject matter of cancelled or withdrawn claims.

Claims 80, 81, and 83-93 have been amended herewith to replace the phrase “protective antibodies” with “bactericidal antibodies.” Support may be found throughout the specification, and specifically at page 5, lns. 3-18.

No new matter has been introduced.

Claim Rejections – 35 U.S.C. §112, first paragraph

The Examiner contends that the instant specification, Declaration of Dr. Francis Michon, and Sabharwal publication, and based on what was commonly known in the art at the time of filing, do not enable a method of eliciting a “protective” immune response specific to group A streptococcal polysaccharide in a mammal as claimed in claims 80-81, and 83-93 which stand rejected under 35 U.S.C. §112, first paragraph. Applicants respectfully disagree, but have amended the claims to replace “protective antibodies” with “bactericidal antibodies” in order to address the Examiner’s concerns. Support may be found throughout the instant specification and specifically at page 5, lns. 3-18. The instant specification is enabling with respect to the scope of the claims as amended and provides sufficient direction and guidance needed to practice the invention. The amount of direction provided by the applicants is sufficient to enable one skilled in the art to administer the claimed conjugate containing the epitope responsible for producing bactericidal antibodies against infection by group A streptococcal bacteria.

The claimed conjugate would be readily constructed by one skilled in the art after reading pages 12-18 of the instant specification. As previously mentioned, the instant specification provides sufficient details and guidance enabling one skilled in the art to make and use the group A streptococcal polysaccharide-protein conjugate for eliciting bactericidal antibodies. In view of the above arguments and amended claims, applicants respectfully request reconsideration and withdrawal of this §112, first paragraph rejection.

35 U.S.C. §112, Second Paragraph Rejections

Claims 80, 81, and 83-93 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Applicants respectfully disagree with the Examiner's contention that these claims are indefinite.

Specifically, Claim 80 allegedly lacks proper antecedent basis in the second recitation of "a mammal." The Examiner contends that Claim 80 also lacks proper antecedent basis in the second recitation of "or protein fragment." Applicants have amended Claim 80 in order to address the Examiner's concerns. Reconsideration and withdrawal of this 35 U.S.C. §112, second paragraph rejection is respectfully requested.

Claim 91 has been rejected under 35 U.S.C. §112, second paragraph for using a trademark or trade name in a claim as a limitation to identify or describe a particular material or product. Applicants respectfully disagree with the Examiner's contention that the term "QS21" is a trademark or trade name. "QS21" is a saponin isolated from the bark of the *Quillaja Saponaria* Molina tree. The term is commonly known and understood in the art. Applicants respectfully point to U.S. Patent No. 6,558,670, enclosed herewith, which reports of vaccine adjuvants and claims the use of saponins, including QS21 without any indication of trademark status. See, col. 2, lns. 3-11, 18-29; col. 4, lns. 8-15, 36-45; and Claim 2.

Additionally, a trademark or trade name search of the USPTO Trademark database was performed for "QS21" or "QS-21;" however, no results were produced. A search of the Sigma-Aldrich catalog resulted in saponin of *Quillaja* bark, but not "QS21." Applicants respectfully request reconsideration and withdrawal of this 35 U.S.C. §112, second paragraph rejection.

With respect to Claims 81 and 83-93 which depend from Claim 80, applicants have amended the base Claim 80 to overcome indefiniteness and vagueness rejections, thus the indefiniteness and vagueness rejections of claims 81 and 83-93 are now moot. Applicants respectfully request reconsideration and withdrawal of this §112, second paragraph rejection.

CONCLUSION

Applicants respectfully submit that the instant application is in condition for allowance. Entry of the amendment and an action passing this case to issue is therefore respectfully requested. In the event that a telephone conference would facilitate examination of this application in any way, the Examiner is invited to contact the undersigned at the number provided.

Allowance of the pending claims is respectfully requested. Early and favorable action by the Examiner is earnestly solicited.

AUTHORIZATION

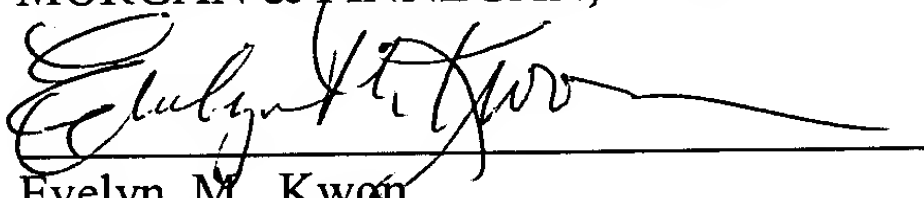
The Commissioner is hereby authorized to charge any additional fees which may be required for the timely consideration of this amendment under 37 C.F.R. §§ 1.16 and 1.17, or credit any overpayment to Deposit Account No. 13-4500, Order No. 2016-4005US1.

Respectfully submitted,

MORGAN & FINNEGAN, L.L.P.

Dated: October 6, 2004

By:



Evelyn M. Kwon

Registration No. 54,246

Correspondence Address:

MORGAN & FINNEGAN, L.L.P.
345 Park Avenue
New York, NY 10154-0053
(212) 758-4800 Telephone
(212) 751-6849 Facsimile